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Randolf Von Oepen

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06/11/2010

WORKMAN NYDEGGER
1000 EAGLE GATE TOWER,
60 EAST SOUTH TEMPLE
SALT LAKE CITY, UT 84111

EXAMINER

SONNETT, KATHLEEN C

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

Claim Objections

1. Claim 44 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In particular, the limitation of claim 44 already appears in claim 36. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is further noted that "a central region" in claim 44 should read "the central region" as it is already referred to in claim 36.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 47-49** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 from which claims 47 and 48 ultimately depend includes that the bar is solid except for a first bore extending laterally through the central region. However, claims 48 and 49 include a second bore extending laterally through the bar. Therefore, these claims are indefinite as it is unclear how the bar can be solid except for a first bore while at the same time containing a second bore. Claims 48 and 49 are also in improper dependent form for failing to further limit the subject matter as they appear to contradict claim 36, not further limit it. Claim 47 similarly includes a bore in a distal region of the bar. Although the claim includes the first bore "coupled to" a distal region of the bar, it appears that this is meant to read "disposed in" a distal region of the bar. Claims 48 and 49 have not been further treated on the merits since it is unclear how the claim can meet both the limitations of being solid except for a first bore while also containing a second bore. However, applicant is directed to US 6,033,430 to Bonutti which

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discloses that a solid bar with two lateral bores is well known (figs. 20-22). Claim 47 has been included in the prior art rejections in the case that the bore is merely “coupled” to a distal region which could mean that it is disposed in the central region.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 36, 38, 39, and 44** are rejected under 35 U.S.C. 102(e) as being anticipated by Swanstrom (US 6,626,919). Swanstrom discloses an apparatus capable of facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising an elongate bar (49; fig. 14) having proximal and distal ends and a longitudinal axis extending therebetween and a central region disposed between the ends, the bar being a solid piece of material except for a first bore extending laterally extending laterally through the central region and generally perpendicular to the longitudinal axis, a filament (48) having first and second free ends, the filament being slidably disposed through and slidably removable from the first bore, the bar being slidable relative to the filament, and a delivery sheath (17) having proximal and distal ends, a lumen extending therebetween to contain the bar and filament (see figs. 5-7 which shows the bar and at least a portion of the filament within the lumen), and a sharpened tip (18) at the distal end. The filament is capable of being slidably removed from the first bore by untying knot (41).

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6. Regarding claim 38, element (20) can be considered a push rod.
7. Regarding claim 39, the bar is rectangular for example as shown in fig. 14.
8. Regarding claim 44, the first bore is in the central region of the bar.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 36, 38-40, and 44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (5,980,559) in view of Kim (US 5,810,884). Bonutti '559 discloses an apparatus for facilitating sealing of a puncture formed in a proximal later surface of a vessel, the apparatus comprising a bar (20d; fig. 9) having proximal and distal ends and a first bore (30d; fig. 9) extending laterally therethrough and a filament having first and second free ends, the filament being slidably disposed through and slidably removable from the first bore, the bar being slidable relative to the filament. The bar is a solid piece of material except for the first bore. It is noted that the claim does not include that this solid piece of material is of uniform composition throughout. That is to say, the two different compositions (144, 146) of the bar shown in fig. 9 make up a solid piece of material. Since holes (150) do not pass through the bar, they may be considered indentations and the bar is still solid other than the first bore (30d) as this is the only bore that passes completely through the bar. Bonutti '974 discloses a delivery sheath in which the filament and bar are disposed but fails to disclose a sharpened tip at the distal end.

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11. However, Kim teaches that it is well known in the art to include a sharpened tip (48) on the distal end of a delivery device used to deliver a suture retaining element. The sharpened tip is tapered which facilitates its insertion into tissue and is advantageous because the same instrument can be used to both form the channel to the surgical site and deliver the sealing instrument to that site. It would have been well within the purview of one skilled in the art to use such a sharpened tip on the delivery sheath of Bonutti '974 as taught by Kim because one skilled in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

12. Regarding claim 38, the device further comprises a push rod (82) disposed in the lumen proximal of the bar.

13. Regarding claim 39, the bar is cylindrical.

14. Regarding claim 40, biodegradable bars are well known as disclosed by Bonutti and it would have been obvious to construct the bar of fig. 9 out of biodegradable materials so that eventual removal is unnecessary.

15. Regarding claims 44, the bore is in the central region.

16. **Claims 41-43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti '559 in view of Kim as applied to claim 36 above and further in view of Nash et al. (US 5,411,520; "Nash"). Bonutti '559 in view of Kim discloses the invention substantially as stated above but fails to disclose a tensioning device configured to hold the filament in a tensioned stated.

17. However, Nash discloses that it is old and well known in the art to include a tensioning device in devices used to facilitate the sealing of a puncture. Nash discloses that such a tensioning device is necessary in order to maintain appropriate tension of the filament while the

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delivery sheath is removed (col. 14, ll. 29-35). The tensioning device is shown in figs. 13, 14, and 26. It comprises an upright (142) having upper and lower ends, a plurality of legs attached to the lower end, and a grip affixed to the upper end. The legs are being considered the two pieces defined by the slit (142D) at the lower end of (142) and the grip is the portion attached to the upper end of (142) that also has a slit (142D). Regarding claim 43, the grip comprises a V-shaped groove formed in the tensioning device formed in the flexible material of the tensioning device, which is being considered an equivalent alternative to an elastomeric material. Although the material can be plastically deformed, it would have been obvious to one skilled in the art to use an elastomeric material since one skilled in the art would have recognized the advantage of having a groove that, in its closed state with no filament therein, is thinner than the diameter of the filament in order to have a stronger grip on the filament. In order to place the filament in such a groove, a material such as an elastomeric material that can be deformed but returns back to its original configuration would have been an obvious material choice to one skilled in the art. It would have been within the purview of one skilled in the art to be able to form grips similar to the louvers with an elastomeric material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Bonutti '559 to include a tensioning device as made obvious by Nash in order to gain the advantage of maintaining appropriate tension of the filament while removing the delivery sheath.

18. **Claims 45-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti '559 in view of Kim as applied to claim 36 above and further in view of Rollero et al. (US 6,506,197; "Rollero"). Bonutti '559 in view of Kim discloses the invention substantially as stated above including the use of either a bore or an eyelet through which a filament is threaded since Kim teaches threading a filament (14) through an eyelet (104). Kim further teaches using an eyelet and bore on the same bar (fig. 9a) so that a filament (14) may be threaded through both

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for additional control over the bar. Bonutti '559 in view of Kim fails to disclose the filament slidably disposed through the first bore, then the eyelet, then back through the first bore.

19. Rollero discloses that it is old and well known in the art to include a plurality of attachment points, such as holes, in a bar such that a filament can be securely attached to the bar (see fig. 6a and 6b). This configuration includes a bore in the central region and in the distal region when the bar is inserted using the delivery sheath of Bonutti '559. The filament is disposed through a central bore, then a bore in a distal region of the bar, then back to the central bore in order to provide a more secure attachment of the bar to the filament (see figs. 6a-6c). It would have been obvious to one of ordinary skill in the art to employ a plurality of attachment points through which the filament is slidably disposed as made obvious by Rollero in the device of Bonutti '974 so that suture can be attached to the bar more securely if desired.

20. **Claims 73-78** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti '559 in view of Bonutti (US 5,814,073; "Bonutti '073) and Kim. Bonutti '559 discloses an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising an elongate bar (fig. 9) having proximal and distal ends and a central region disposed between the ends, the bar being a solid piece of material except for a first bore (30d) extending laterally through a central region as discussed above in more detail, the bar having a distal end having a generally planar surface oriented parallel to the bore, a filament having first and second free ends, the filament being slidably disposed through and slidably removable from the first bore, the bar being slidable relative to the filament, and a delivery sheath (80) having proximal and distal ends, and a lumen extending therebetween to contain the bar and filament. Bonutti '559 fails to expressly disclose that the delivery sheath has a sharpened tip at the distal end that is disposed upon a peripheral longitudinal side of the delivery sheath and also fails to disclose an eyelet.

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21. However, Bonutti '073 teaches that it is well known to use an inserter with a sharpened tip at its distal end that is disposed upon a peripheral longitudinal side of the delivery sheath (figs. 5-9). The sharpened tip facilitates insertion of the anchor into tissue and is advantageous because the same instrument can be used to both form the channel to the surgical site and deliver the sealing instrument to that site. It would have been well within the purview of one skilled in the art to use such a sharpened tip delivery sheath as taught by Bonutti '073 to deliver the bar of Bonutti '559 so that it too may have these advantages. Kim teaches using an eyelet and bore on the same bar (fig. 9a) so that a filament (14) may be threaded through both for additional control over the bar. It would have been obvious to incorporate an eyelet on the device of Bonutti '559 as taught by Kim in order to easily control the orientation of the bar during placement. Although the axes of the eyelet and bore of Kim appear to be perpendicular, it would have also been obvious to orient the longitudinal axes of the two attachment points (bore and eyelet) so that they are parallel since providing multiple attachment points with parallel axes is well known in the art and furthermore, such a modification can be considered a simple rearrangement of parts which involves only routine skill in the art (*In re Japikse*, 86 USPQ 70).

22. Regarding claim 74, the bar of Bonutti '559 is cylindrical (fig. 20).

23. Regarding claim 75, the bar of Bonutti '559 is cylindrical. However, applicant has not disclosed any criticality to the shape of the bar or any advantages associated with a rectangular bar as opposed to a cylindrical bar. Applicant states that "it will be apparent to those skilled in the art that while bars 22 and member 32 of figs. 1a-1d are illustratively shown having cylindrical and oval-shaped configurations, respectively, other configurations advantageously may be provided to perform the functions described hereinbelow". Therefore, it appears to the examiner that, when the prior art teaches a cylindrical bar, it will be apparent to those skilled in the art that other shapes can be used. Furthermore, it has been held that a mere change in shape of an

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element absent persuasive evidence that the particular configuration of the claimed element is significant involves only routine skill in the art (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)).

24. Regarding claim 76, since Kim teaches having the two connection points, one being in the in the central region and one being on one end of the bar, it would have been obvious to incorporate the eyelet on either end of the bar since the bore of Bonutti '559 is already located in the central region and this would allow control over orientation of the bar. Regarding which end the eyelet extends from, it would have been obvious to incorporate the eyelet on either end since both attachment points perform the function of providing a second attachment point to increase control equally well.

25. Regarding claim 77, Bonutti '559 discloses that the resorbable bars are well known and therefore constructing the bar shown in fig. 9 of resorbable material would have been obvious.

26. Regarding claim 78, Bonutti '073 teaches a sheath with a handle disposed at its proximal end (for example, ring 186 of sheath can be grasped).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,694,982 to Latour discloses a bar having a bore in the central region and eyelets on the end of the bar. US 2003/0181946 to Bartlett discloses a bore in a central region of a suture anchor that also includes a tethering hole in the proximal end of the anchor.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 6/8/2010

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/8/10